

7 January 2016 EMA/847935/2015 Information Management Division

Call for expressions of interest, from software vendors, service providers and pharmacovigilance system implementers, to attend a workshop on 4 March 2016 on the implementation of international ICSR standard (ICH E2B(R3))

With this announcement the European Medicines Agency is looking for representatives from software vendors, service providers and pharmacovigilance system implementers (NCAs, MAHs & sponsors of clinical trials) to attend a workshop on implementing ISO ICSR 27953-2:2011 (ICH E2B(R3)).

In December 2010, new pharmacovigilance legislation (Regulation (EU) No 1235/2010 amending Regulation No 726/2004 and Directive 2010/84/EU amending Directive 2001/83/EC) was adopted by the European Parliament and European Council. Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 require the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines. These articles specifically reference the use of the ISO ICSR standard that was finalised in 2011 and to its supporting terminologies such as MedDRA which are further explained in an associated ICSR implementation guide.

The Agency, in consultation with the EU regulatory network, has produced and published additional technical documentation that is intended to assist in the implementation of the ISO ICSR standard.

The Agency as part of the EU Regulatory Network wishes to provide a forum where industry and regulators are able to openly discuss the technical aspects of the implementation of the ISO ICSR standards in Europe. It is foreseen that this workshop would include participation from software vendors and service providers as well as implementers of pharmacovigilance systems.

Workshop Topics

The key workshop topics to be covered are given below and it should be noted that attendees are expected to already be familiar with all the published ICH and EU technical documentation on ISO ICSR. This workshop will focus on technical IT aspects of implementing HL7 XML messages. Therefore, this workshop would not be suitable for people without an IT background or relevant IT experience. Organisations are encouraged to submit questions ahead of the workshop for inclusion in a question and answers session. In addition, if organisations wish to give presentations on ISO ICSR implementation please contact the EMA with the e-mail address given below with details of your proposed presentation.



Key workshop topics:

- ICH/EU Implementation Guides
- ICH/EU Reference Instances
- · ICH/EU Code lists
- ICH Technical info document
 - XPATHS
 - Dosing/Intervals of time (Overview)

- Backwards/Forwards Conversion
- EU Testing process
- · ICSR Export manager
- Nulflavors
- UUIDs
- UCUM PQ data type

Application procedure and closing date

Interested parties may nominate two people from their organisation to attend the workshop that will be held on 4th March 2016. As there are limited spaces available, places for attendees will be made on first come first served basis with the aim to provide as many organisations the chance to participate. If the workshop is oversubscribed then we may restrict attendance to one person per organisation.

A minimum of thirty-one places will be reserved for National Competent Authorities (NCAs). Each NCA may nominate one person to attend the workshop whose attendance will be reimbursed, they may also nominate one additional person (who will not be reimbursed).

Expressions of interest should be sent by 1^{st} February 2016 to the following email address: ISOICSR@ema.europa.eu. The subject of the email should contain the phrase "EU ISO ICSR workshop: March 2016".

The Agency will review the applications and will inform attendees before 15 February 2016.

EMA/847935/2015 Page 2/2